

REMARKS

This is in response to the Office Action mailed on March 25, 2005. Claims 2-37 are pending in the application. Claims 1, 6, 7, 32, and 33 have been cancelled. Claims 2, 5, 8, 9, 10-12, 14, 15, 17, 19, 21, 23, 30, 31 and 34 have been amended.

The above-noted amendments to the claims are respectfully submitted in order to more clearly and appropriately claim the subject matter which applicants consider to constitute their invention and to correct informalities such as claim dependencies. No new matter is included in these amendments.

Turning now to the merits of the outstanding office action, the Examiner rejected claims 1-4, 6-31 and 33-37 under 35 U.S.C. § 112, second paragraph, on the grounds that no chemical structures have been provided showing how the two compounds are complexed and that the amino acids can complex to differing locations on the tin mesoporphyrin. This rejection is respectfully traversed.

The second paragraph of 35 U.S.C. § 112 states:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

According to MPEP Section 2171, there are two separate requirements set forth in this paragraph:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The Examiner has indicated that the rejected claims allegedly do not meet either criteria under 35 U.S.C. § 112, second paragraph. Applicants respectfully submit that the claims are indeed definite and distinctly claim the subject matter they regard as their invention.

Regarding, indefiniteness, MPEP Section 2173.02 states:

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.

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The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph by providing clear warning to others as to what constitutes infringement of the patent.

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If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. 112, second paragraph is appropriate, such a rejection should be made and an analysis as to why the phrase(s) used in the claim is "vague and indefinite" should be included in the Office Action.

Applicants respectfully submit the second paragraph of 35 U.S.C. § 112 does not require that the structures of the complexed compounds to be shown in the specification or in the claims. Tin mesoporphyrin compounds, examples of which include tin mesoporphyrin halides such as tin mesoporphyrin dichloride shown in the Figures, are well-known in the art. "Complexed" is a term that is also well-known in the art, which refers to the association of two or more molecular entities. A person of skill in the art could immediately determine what is meant by a tin mesoporphyrin in association with an amino acid, and the specification does not need to include description of that which is well-known in the art.

Claims 2, 11 and 34 have been amended to include the language "at least one" to precede amino acid, obviating the rejections of claims 4 and 14, which depend from claim 2. Claim 21 has been amended to clarify the claim language and to indicate a specific process for producing a tin mesoporphyrin and to remove "IX" from the claims, which was a typographical error.

Regarding the rejection of claim 23, the term hydrogenation catalyst is a term having a well-known meaning to those of ordinary skill in the art. Without intending to limit the invention, suitable hydrogenation catalysts include palladium on carbon, which is described in United States Application Serial No. 10/453,815, now United States Patent No. 6,818,763.

The claims clearly apprise one of ordinary skill in the art the metes and the bounds of the invention. Considering the state of the prior art and that tin mesoporphyrin compounds are known compounds as illustrated in the specification, applicants respectfully submit that the claims apprise one of ordinary skill in the art of their scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph,

by providing clear warning to others as to what constitutes infringement of the patent. The claims thus meet the requirements of 35 U.S.C. 112, second paragraph.

Turning now to the rejections under 35 U.S.C. 103(a), the Examiner rejected the claims as allegedly being obvious over Robinson (US2003/0100752A1) ("Robinson") and Niedballa et al. (US 5,275,801) ("Niedballa"). These rejections are respectfully traversed.

Claims 1-10, 22, 32-35 and 37 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Robinson. The Examiner states that Robinson teaches a tin mesoporphyrin compound complexed with a second agent, where the second agent is an amino acid, as well as methods of treating various disorders using the complexes. Applicants respectfully disagree with the Examiner. Robinson does not teach or suggest a tin mesoporphyrin complexed with a second agent, such as an amino acid. Robinson teaches metallotetrapyrrolic derivatives that contain at least one complexing agent to which at least two metal ions are attached. (Page 5, para. 22 to page 7, para. 38.) The metallotetrapyrrolic derivatives can contain amino acid side groups. Nowhere does Robinson teach or suggest that underivatized tin mesoporphyrin is directly complexed with a second agent, such as an amino acid. The Examiner's reference to mesoporphyrin in Table 1 is misplaced because paragraph 159 clearly states that the compounds in Table 1 "are particularly preferred as starting materials for the synthesis of the compounds of structures I-IV," none of which are a tin mesoporphyrin. (emphasis added.) Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claims 11-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Niedbella et al.. The Examiner states that Niedbella teaches a method for producing a water-soluble tin mesoporphyrin/amino acid complex. Applicants respectfully disagree with the Examiner. Niedbella does not teach or suggest a tin mesoporphyrin complexed with a second agent, such as an amino acid. Niedbella teaches deuteroporphyrin and hematoporphyrin derivatives that contains a complexing agent K to which a metal can be attached. (Col. 13, lns. 59 to col. 14, ln. 2.) Any acidic groups of deuteroporphyrin and hematoporphyrin derivatives can be neutralized with basic amino acids, such as lysine, arginine or ornithine. (Col. 14, lns. 3-12.) Nowhere does Niedbella teach or suggest that tin mesoporphyrin can be directly complexed with a second agent, such as an amino acid,

without the need for derivatization. Accordingly, Applicants respectfully request that the rejection be withdrawn.

In view of the above, it is respectfully requested that these amendments be entered, and that prosecution on the merits of this application now be initiated. In view of the foregoing remarks, the application is believed to be in condition for allowance, and early notice to this effect is earnestly solicited.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 50-3329 therefor.

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Respectfully submitted,

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